

## **REMARKS**

### **I. Introduction**

Claims 14, 16 – 22, and 24 – 55 are currently pending. The Examiner had listed claim 15 as pending; however, claim 15 was previously canceled. For avoidance of doubt, Applicants following entry of the present amendment claim 15 is now canceled, and claims 14, 16 – 18, 26, 27, 29 – 33, and 37 are amended. It is believed no new matter has been added.

### **II. Rejections under 35 USC § 112 – Written Description**

Claims 16, 30 – 37, 48 and 55 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the term “constituent” does not meet the written description requirement as the term may encompass other components including water or a polymer. Applicants respectfully traverse the rejection; however, have amended claims 16 and 37 to recite that the constituent is selected from therapeutic materials, and decorative materials in order to advance prosecution.

### **III. Rejections under 35 USC § 112 - Indefiniteness**

Claims 14, 15, 17, 18, 26, 27, and 29 – 33 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner asserts that the claims lack antecedent basis for the term “the film flake”. In response, Applicants have amended claims 14, 17, 18, 26, 27, and 29 – 33, and request that the rejection be withdrawn.

### **IV. Rejections under 35 USC § 103(a)**

*A. Claims 16 – 17, 24, 28 – 32, 34 – 37, 40 – 42, 47, 52 and 55 are rejected under 35 USC 103(a) as being unpatentable over Hauschild et al. (US 4,440,877).*

The Examiner asserts that Hauschild et al. discloses toothpaste compositions comprising functional agglomerated speckles which comprise ethyl cellulose and a water soluble polymer. The water soluble polymers may include carboxymethyl hydroxyethyl celluloses, starches and hydroxypropyl methyl cellulose. The Examiner finds that Hauschild et

al. does not disclose that the speckles are flakes, but matters relating to ornamentation cannot be relied upon to patentably distinguish the claimed invention from the prior art. Thus, the Examiner asserts, it would have been obvious to one of ordinary skill in the art to have made a flake instead of speckles in order to practice the presently claimed invention.

Applicants respectfully traverse the rejection, and request reconsideration as a *prima facie* case of obviousness has not been established.

The obviousness determination requires four kinds of factual inquiries:

- (1) the scope and contents of the prior art;
- (2) the differences between the prior art and the claims at issue;
- (3) the level of ordinary skill in the pertinent art; and
- (4) any objective indicia of success such as commercial success, long felt need, and copying.

*KSR Int'l. Co.*, 127 S. Ct. at 1735 (citing *Graham v. John Deere Co.*, 383 US 1, 17-18 (1966)). The Supreme Court in *KSR* recognized that a showing of "teaching, suggestion, or motivation" to combine prior art could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 USC 103(a). *Id.* at 1741. The Supreme Court specifically stated that "it will be necessary . . . to determine whether there was an apparent reason to combine [or modify] the known elements [in the prior art] in the fashion claimed by the patent at issue. To facilitate review, this analysis *should be made explicit.*" *Id.* at 1740 - 41 (emphasis added).

#### 1. The scope and content of the Prior Art and Differences Between the Prior Art and Claimed Invention:

The present invention is directed to a dentifrice composition comprising an orally acceptable vehicle having distributed therein flakes. The flakes are formed from a water hydratable film matrix, and the matrix comprises a water soluble hydroxyalkyl cellulose polymer. The flakes also contain a constituent, and are present from about 0.05 to about 1.0% by weight of the composition.

In contrast, Hauschild et al. discloses speckles which may be incorporated into dentifrice compositions. The speckles are agglomerates of a water insoluble powdered functional material, and a binder, which includes a water insoluble ethyl cellulose binder and a water soluble binder, such as sodium carboxymethyl cellulose, starch, and hydroxypropyl methyl cellulose.

2. The Obviousness Determination:

- a. The reference fails to disclose all of the limitations of the claims.

The Examiner has acknowledged that Hauschild fails to discloses that the agglomerates are flakes.

b. *There is no teaching or suggestion to practice the presently claimed invention*

The teachings of Hauschild et al. are directed to very specific agglomerate speckles containing a functional material and binders. The binder is a mixture of ethyl cellulose and a water soluble binder. Referring to Example 6 of Hauschild et al., it is clear that compositions which lack ethyl cellulose rapidly degrade and are unsuitable for intended use. In contrast, the present invention is directed to oral compositions containing flakes which comprise a water soluble hydroxalkyl cellulose polymer, and no ethyl cellulose is required.

Finally, there is no teaching or suggestion to produce the agglomerate speckles of Hauschild et al. as flakes. Hauschild et al. states that the size of the binder components is of relatively little importance; however, fails to suggest producing the agglomerates as flakes, as the entire disclosure is limited to the production of powders which are agglomerated. Moreover, Hauschild et al. describes carboxymethyl cellulose, starch, and hydroxypropyl methyl cellulose as *binders*, which is indicative of agglomerates, not flakes.

c. *There is no reasonable expectation of success in practicing the claimed invention based on the disclosure of Hauschild*

Hauschild makes clear that ethyl cellulose is critical to the speckles. Referring to Example 6, it is seen that the compositions which lack ethyl cellulose rapidly degrade. Based on a fair reading of Hauschild, one of skill in the art could not reasonably expect to produce a stable flake in the absence of ethyl cellulose. Indeed, based on a fair reading of Hauschild et al., one of skill in the art would not seek to produce flakes which comprises a matrix of a water soluble hydroxalkyl cellulose polymer. Applicants respectfully submit that Hauschild et al. actually teaches away from the present invention.

d. *Conclusion*

It is clear that the present claims are not obvious over the disclosure of Hauschild et al. The differences between the disclosure and the present invention are so dramatic that Hauschild et al. cannot be said to teach or suggest all of the limitations of the claims. Furthermore, Hauschild et al. teaches away from the present invention. Applicants respectfully submit that a *prima facie* case of obviousness has not been established, and requests the rejection be withdrawn.

*B. Claims 14, 15, 20-22, 25-27, 38, 39, and 43 – 54 are rejected under 35 USC 103(a) as being unpatentable over Hauschild et al. (US 4,440,877) in view of Rajaiah et al. (US Pat. Pub. 2002/0187108).*

The Examiner has relied upon Rajaiah et al. as a general disclosure as to components used in therapeutic components in oral compositions. Applicants respectfully traverse the rejection and request reconsideration. As Hauschild et al. fails to teach or suggest all of the limitations of independent claims 16 and 37, it cannot teach or suggest all of the limitations of the claims that depend therefrom, either alone or in combination with Rajaiah. Applicants respectfully request that the rejection be withdrawn.

V. Conclusion

In view of the amendments and remarks contained above, Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that a Notice of Allowance be issued. If any remaining matters need to be resolved, Applicants respectfully request an interview with the Examiner prior to any official action being taken by the Office in response to these arguments and amendments in order to facilitate allowance of the pending claims.

It is believed no fees are presently required. If any fee is required, please charge the same to Deposit Account 03-2455.

Respectfully submitted,

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